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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,271	04/12/2001	William Widner	5455.210-US	4969

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EXAMINER	
MONSHIPOURI, MARYAM	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/834,271	WIDNER ET AL.	
	Examiner	Art Unit	
	Maryam Monshipouri	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 74-93 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 74-93 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-73 have been canceled. Claims 74-93 are still at issue and are present for examination.

Applicants' arguments filed on 7/12/04 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 74-93 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitations introduced to the end of claim 74 starting with " wherein the mRNA processing stabilizing sequence is foreign to the consensus promoter...." Do not appear to have support in the specification. Hence, for examination purposes said amendment to claim 74 is considered to be **new matter**. Applicant is advised to either refer the examiner to the part of specification wherein the explicit teaching of said amendment is originated from or possibly rewrite said claim. Claims 75-93 are rejected merely for depending from a rejected base claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 74-77, 80, 82-84, 86-88 and 91-93 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hung (cited previously) in view of Lereclus (cited previously) according to previous office action. In traversal of this rejection applicant argues that : Lereclus presents contradictory data that placing the cryIIIA "downstream region" (also known as the cryIIIA "mRNA processing /stabilizing sequence") downstream of a heterogonous promoter has any positive effect on gene expression. In support of his opinion applicant points to figures 4 and 5 and pages 33-34 wherein the expression results of pHT901'lacZ (wherein lacZ promoter is situated upstream of the "downstream region" upstream of lacZ gene) and pHT304'lacZ control plasmid (wherein the downstream region is absent and lacZ gene is only driven by lacZ promoter alone) show no positive effects due to " downstream region's " presence. He then refers to figures 4 and 6 of Lereclus, wherein the construction of (a) pHT7902'lacz where cryIIIA promoter is upstream of the lacZ gene and (b) control pHT907'lacz (figure 6) where the cryIIIA "downstream region " is absent, are disclosed and indicates that figure 6 does show that pHT7902'lacz construct increases expression of lacZ gene relative to the pHT7907'lacz construct.

Applicant then concludes that while Lereclus shows that the cryIIIA "downstream region" located downstream of the cryIIIA promoter has a positive effect on the

expression of the cryIIIA gene, there is no unequivocal evidence presented that the cryIIIA downstream region" can be used with other promoters that are foreign to the cryIIIA "downstream region" to increase expression of a gene. In fact, based on the results of Lereclus the cryIIIA "downstream region" appears to be specific for the cryIIIa promoter.

Applicant then continues by stating that since the references cited by the examiner do not contain the requisite teaching, they cannot be combined to support the obviousness rejection. Further, there is no motivation to insert the "downstream region" of Lereclus in to the DNA construct of Hung because there is no reasonable expectation of success of increasing expression of a gene based on the results obtained by Lereclus wherein the mRNA processing/stabilizing sequence is foreign to the consensus promoter and therefore the rejection should be withdrawn.

These arguments were fully considered but were found **unpersuasive**. In response to applicant's arguments it should be noted that In figure 4, Lereclus is trying to pinpoint the region within the bacillus promoter that regulates/impacts DNA transcription and its positioning relative to "downstream region" such that the construct would be functional. In contrast to applicant's view the examiner is of the opinion that Lereclus in figure 4 is displaying that mere insertion of "downstream region" in the lacZ promoter (which could possibly result in disruption of promoter regulating region) is not increasing lacZ expression, significantly, as evidenced by results illustrated in figure 5 (see pHT7901'lacz). It further illustrates this fact by preparing pHT7902'lacz (wherein the positioning of all construct compenets are proper) and showing its performance in

increasing/enhancing expression of lacZ gene in both figures 5 and 6. Thus, in view of the examiner Lereclus is not indicating that placing downstream region, downstream of lacZ promoter and upstream of lacZ gene has no positive impact on lacZ gene expression. Rather, Lereclus data is positively indicating that appropriate positioning of each element of the construct (i.e. promoter, "downstream region etc.) and/or its critical regulatory regions plays a role on enhanced gene expression in his constructs. Therefore, there is no condradiction in results displayed by Lereclus and all requisite teachings are present therein.

Further, the examiner respectfully disagrees with the applicant that Lereclus provides no unequivocal evidence that its cryIIIa downstream region can be used with other promoters that are foreign to said "downstream region" to enhance recombinant gene expression. This is because in column 2 of U.S. patent 6,140,104 (also cited by the applicant as the U.S. patent corresponding/equivalent to Lereclus French patent) Lereclus teaches that the promoter used in his constructs may be both endogenous and exogenous to the host used (see column 2) so long as it is functional. Furthermore, with respect to "downstream region" Lereclus also indicates that apart form the exact sequences of the "downstream region" those that can hybridize thereto, under non-stringent conditions may be used (see column 60) suggesting flexibility in compositions of "downstream region (which could inherently originate from other species) that may be utilized in its constructs. Therefore in view of said evidence, in contrast to applicant's view one of ordinary skill in the art is motivated in combining promoters which may be foreign to said "downstream region" or homologs thereof with a reasonable expectation

of obtaining enhanced expression of genes in bacillus and even some other hosts (as disclosed in column 9 of Lereclus U.S. patent. Hence the rejection is maintained for the reasons explained here, in addition to those provided in the previous office action.

Claims 89-90 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hung (cited previously) in view of Lereclus (cited previously) further in view of Jorgensen (cited previously) according to previous office action. In traversal of this rejection applicant relies on the same arguments summarized and addressed above. Hence, the rejection remains for the reasons explained above, as well reasons provided previously.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 4:30 p.m. except for alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnanthapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Monshipouri

Maryam Monshipouri Ph.D.

Primary Examiner

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